

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance.

Claims 56-75 are pending in the application. Support for claims 56-75 may be found generally throughout the specification and in the original claims. In particular, the Examiner's attention is respectfully directed to original claims 1-18 and the present specification at page 4, lines 16 to page 5, lines 28; page 8, lines 9-14; page 9, lines 15-27; page 10, lines 15-20; and page 11, lines 1-3.

Claims 1-55 are canceled without prejudice or disclaimer and may be the subject of a future application.

In the outstanding Official Action, claims 43 and 45 were objected to for allegedly containing several informalities. Applicants respectfully submit that the present Amendment overcomes this objection.

Claims 43 and 45 are canceled. Applicants respectfully submit that new claims 56-75 have been drafted in a manner that avoids these informalities. Applicants respectfully request that the objection be withdrawn.

Claims 36-55 were rejected under 35 U.S.C. §112, first paragraph, for allegedly not satisfying the enablement requirement. This rejection is traversed.

Applicants respectfully submit that the rejection has been rendered moot with the cancellation of claims 36-55.

Nevertheless, Applicants note that the outstanding Official Action cites to three (3) articles in support of the rejection. Applicants respectfully submit that none of these articles evidence that the claimed invention does not satisfy the enablement requirement.

The DUNCAN article studies the entry of microorganisms through Caveolae. DUNCAN discloses that caveolae and lipid rafts have been increasingly recognized as a significant entry point for microorganisms to enter a host cell.

However, while DUNCAN studies a particular pathway, DUNCAN neither discloses nor suggests that this is the only entry point or pathway in which a

microorganism can enter into a host cell. Independent claim 56 recites a method for reducing the invasion and infection of mammalian cells by pathogenic intracellular bacteria selected from the group consisting of *E. coli*, *Listeria* and *Salmonella*. DUNCAN does not cast any doubt as to whether the claimed invention is satisfied by the disclosure.

The JUTRAS article studies whether cholesterol-rich domains participate in the entry of microorganisms into host cells. In this regard, the article is irrelevant for purposes of determining whether the claimed invention is enabled, as JUTRAS does not study the inhibitory effect of cycloglycan on *E. coli*, *Listeria* and *Salmonella*.

Nevertheless, Applicants note that contrary to the assertions of the Official aCtion, Fig. 2C on page 264 shows that the administration of methyl β -cyclodextrin reduces inhibition of *E. coli* into CHO cells (i.e., 8% to less than 6%). In this regard, Applicants respectfully submit that JUTRAS actually evidences the fact that the claimed invention satisfies the enablement requirement.

ROTH discloses the use of β -cyclodextrin for inhibiting HIV-1 entry. However, sole, independent claim 56 recites a method for reducing the invasion and infection of mammalian cells by particular pathogenic intracellular. In that ROTH is concerned with viruses and the claimed invention is concerned with bacteria, Applicants respectfully submit that ROTH is irrelevant for determining whether the claimed invention is enabled or not.

The Examiner is respectfully reminded of the well founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by the evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the

part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Ngiyen and Stanhagen*, 181 USPQ 46 (CCPA 1974):

Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported in evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification.

In view of the above, Applicants respectfully submit that none of the publications should be considered as evidence that the claimed invention is not enabled by the present disclosure. Applicants respectfully request that the rejection be withdrawn.

Claims 45 and 46 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite.

Claim 45 was rejected for reciting the term "a probe." Applicants respectfully submit that one skilled in the art would understand that the use of the term "probe" within the context of the claimed invention is definite. For example, the Examiner's attention is respectfully directed to page 9, lines 25-27, wherein the application of the term "probe" is used within the context of a food.

Claim 46 was rejected for reciting the phrase "the composition as a pharmaceutical composition in a form for." The claims have been drafted to avoid this phrase.

Applicants respectfully request that the rejection be withdrawn.

Claims 36 and 38-55 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by YOSHIKUMI et al. This rejection is traversed.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Akzo N.V. v. International Trade Comm'n, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.).

Applicants respectfully submit that YOSHIKUMI fails to disclose or suggest treating a subject having a disorder caused by *E. coli*, *Listeria* and *Salmonella*, as recited in sole independent claim 56. YOSHIKUMI discloses at col. 3, lines 64-66, that the disclosed composition can "bring about the improving effect on the symptoms of intestinal diseases". However, YOSHIKUMI does not disclose or suggest the symptoms or disease are caused by any particular bacterium.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the

prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

YOSHIKUMI does not necessarily show that the symptoms relate to a disease caused by one of the bacterium recited in claim 56. In this regard, Applicants also respectfully directed to dependent claims 72-74, wherein the bacterium of claim 56 are further characterized.

YOSHIKUMI does not disclose a particular type of a subject, as recited in claim 75.

In view of the above, Applicants respectfully submit that YOSHIKUMI fails to anticipate the claimed invention.

Claims 36-51 and 53 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Anand et al. Claims 36-43, 46, 48-51 and 53 are rejected

under 35 U.S.C. §102(b) as allegedly being anticipated by ROTH. Claims 36-44, 46 and 48-51 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Nelson. In addition, claims 36-51 and 53 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Bernstein. Claims 36, 38-43, 46-51 and 53 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hermida et al. Applicants respectfully submit that the present Amendment overcomes these rejections.

Previously pending claim 52 was free from each of these rejections. Claim 52 recited administering a cycloglycan to a subject that has a disease caused by a pathogenic, intracellular bacteria. As this subject matter of claim 52 is recited in sole, independent claim 56, Applicants respectfully request that each of the anticipation rejections be withdrawn.

Conclusion

In view of the present Amendment and foregoing Remarks, therefore, Applicants believe that the present application is condition for allowance at the time of the next Official Action. Allowance and passage to issuance is respectfully requested.

Respectfully submitted,

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